

[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development Of Brachyury Tumor Associated Antigens As Cancer Vaccines For Colorectal Cancer.

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Bavarian Nordic Immunotherapeutics ("BNIT") located in Mountain View, CA, USA.

<u>Intellectual Property</u>:

U.S. Provisional Patent Application No. 61/701,528 [HHS Ref. No. E-054-2011/0-US-01] filed September 17, 2012, entitled "Methods and Compositions for the Treatment of Cancer," as well as all international applications, continuation applications and divisional applications.

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use will be limited to the use of Licensed Patent Rights for development of pox virus-based immunotherapeutics for colorectal cancer.

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A. Licensing and Patenting Manager, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5587; Facsimile: (301) 435-4013; E-mail: chatterjeesa@od.nih.gov.

SUPPLEMENTARY INFORMATION:

Cancer immunotherapy is a recent approach where tumor associated antigens (TAAs), which are primarily expressed in human tumor cells and not expressed or minimally expressed in normal tissues, are employed to generate a tumor-specific immune response. Specifically, these antigens serve as targets for the host immune system and elicit responses that result in tumor destruction.

The technology relates to the development of cancer vaccines utilizing pox virus vectors encoding proteins involved in regulating the epithelial-to-mesenchymal transition

(EMT) during vertebrate development, as a cancer antigen. Dr. Jeffrey Schlom et al. at

NCI have demonstrated for the first time that a T-box transcription factor and a molecule

implicated in EMT, namely the Brachyury protein, appears to be highly expressed in

metastasizing tumor cells, and could be a potential target for human T-cell mediated

cancer immunotherapy, such as for tumors of the lung, intestine, stomach, kidney,

bladder, uterus, ovary, testis, colon and chronic lymphocytic leukemia.

The prospective exclusive license will be royalty bearing and will comply with

the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective

exclusive license may be granted unless within thirty (30) days from the date of this

published notice, the NIH receives written evidence and argument that establishes that

the grant of the license would not be consistent with the requirements of 35 U.S.C. 209

and 37 CFR Part 404.7.

Applications for a license in the field of use filed in response to this notice will be

treated as objections to the grant of the contemplated exclusive license. Comments and

objections submitted to this notice will not be made available for public inspection and,

to the extent permitted by law, will not be released under the Freedom of Information

Act, 5 U.S.C. 552.

August 13, 2013 Date

Richard U. Rodriguez,

Director

Division of Technology Development and Transfer

Office of Technology Transfer

National Institutes of Health

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